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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,090	10/17/2003	Rubinah K. Chowdhary	273012011601	9064

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/688,090

Applicant(s)

CHOWDHARY ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,7-14,18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7-14,18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input checked="" type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)     | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10-24-03</u>  | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Examiner acknowledges receipt of preliminary amendments to the specification filed 10/17/03 and 04/05/04, IDS filed 11/24/03, preliminary amendment to the claims and remarks filed 04/05/04. Claims 1, 7-14, 18 and 19 are pending.

#### ***Priority***

1. Examiner further acknowledges this application as a continuation of prior application number 09,851,641 filed 08 May 2001, now US 6,693,093. Examiner also acknowledges applicants' claim for benefit of provisional application number 60/202,641 filed 08 May 2000.

#### ***Information Disclosure Statement***

The information disclosure statement filed 11/24/03 as been considered for the US patent. However, applicants indicated that the references were submitted in prior application. The non-patent literature references and the foreign patents are scanned and are made part of the electronic file. Examiner, has thus not considered the non-US documents and respectfully requests applicants to submit those non-US documents including the non-patent literature references and the foreign patents so that they can be scanned and made part of the electronic file.

#### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84. Copy of Form PTO-948 is included with this action.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites what “emulsion forming agent” is excluded from the photosensitizer carrier composition. There is no further recitation or description or listing of what “emulsion forming agent” is included in the carrier composition.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1, 8 and 10 rejected under 35 U.S.C. 102(a) as being anticipated by Rajagopalan et al. (WO 99/51284), reference provided by applicants in Form PTO 1449.

Rajagopalan teaches a composition that comprises non-covalent carrier-hapten complexes of the structure HM---CM, where HM is the hapten and is selected from the group consisting of peptides, carbohydrates, **photosensitizers** and fluorescent dyes; and CM is a carrier molecule where surfactant is one of the carrier molecule (claim 1). Rajagopalan specifically teaches that the photosensitizer has absorption and emission maxima in the range of 200-1200 nm (claims 2, 4, 10, 12 and 18). HM is further selected from the group consisting of cyanine, indocyanine, squaraine, porphyrins, Rose Bengal and methylene blue (claims 6, 15, 22 and 29). CM is a surfactant (claims 5, 8, 11, 13, 17, 19, 21, 24 and 26), polyaspartic acid (claims 7, 16, 23 and 30). Rajagopalan administers the non-covalent carrier-hapten bioconjugate to a patient for diagnostic or therapeutic procedure where the procedure is selected from the group consisting of

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tomographic imaging, fluorescence and absorbance monitoring and endoscopic examinations (claims 8 and 9). Rajagopalan teaches that the hapten is preferably a photosensitizer, which is capable of transferring energy to tissues or to other components inside and outside the cell (page 6, lines 13-15). The composition of Rajagopalan is a solution or liquid or sterile aqueous solution or suspension (page 8, lines 8-18)

Claim 8 of application recites polyaspartic acid as a block copolymer and the drying step in the application is optional (claim 3 and 5). Rajagopalan clearly teaches a liquid composition comprising a photosensitizer and block copolymer where the block copolymer is not a poloxamer 188 or amphiphilic polymer of polystyrene sodium sulphonate and vinyl naphthalene. Therefore, the teachings of Rajagopalan meet the limitations of the claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1 and 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyons (US 5,616,342).

Lyons teaches an emulsion composition that comprises surfactant, co-surfactant and pharmacologically and photoreactive photosensitizing compound and specifically pyrrole-based macrocyclic compounds. The photosensitizing compounds of interest in Lyons are natural or synthetic porphyrins, chlorines, and bacteriochlorins, synthetic isobacteriochlorins, phthalocyanines, naphthalocyanines, porphycenes, sapphyrins and texaphyrins and derivatives

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thereof. Lyons' emulsion composition is utilized in oxygen-dependent and oxygen-independent phototherapy, and the emulsion is capable of being autoclaved. See column 1, lines 9-22, column 2, lines 37-62 and columns 3-7, and claims 20, 21 and 23.

Lyons composition further comprises oils (column 8, lines 1-16) and stabilizer selected from phosphatides, soybean phospholipids, and non-ionic poloxamer block-copolymers, synthetic or semi-synthetic phospholipids with egg yolk phospholipid, the preferred stabilizer (column 8, lines 17-26). The composition further comprises isotonic agents, auxiliary ingredients and solvents (column 8, lines 47-67).

Lyons teaches a method for diagnosing a patient for tumor wherein the method comprises administering the emulsion composition to said patient and then exposing the patient to light that has a suitable wavelength to induce fluorescence of photosensitizing compounds that are maintained by abnormal cells (claim 28). In claims 25 and 27, the emulsion of Lyons is administered to a patient, after which the patient is exposed to light to activate the photosensitizing agent in the emulsion, to treat said patient.

Lyons clearly teaches the composition and the method for conducting photodynamic therapy except that the broad teaching of poloxamer encompasses all forms of poloxamers including poloxamer 188. Thus the expected composition is one that comprises photosensitizing agents, poloxamer block copolymer that may include or exclude poloxamer 188, oil as emulsion forming agent and auxiliary ingredients and solvents for administration to a patient for photodynamic therapy. There is no suggestion in the prior art that poloxamer 188 would be preferred in the composition of the prior art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the photosensitizer

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composition of the prior art where the broad teaching of poloxamer encompasses all poloxamers.

One having ordinary skill in the art would have been motivated to prepare an emulsion composition comprising photosensitizing agents and poloxamer that may include or exclude poloxamer 188. In the absence of a showing of the criticality of excluding poloxamer 188, the claims in the application are not inventive over the prior art.

9. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyons (US 5,616,342).

Lyons is discussed above. Lyons discloses a composition that has a broad teaching of poloxamers. There is no suggestion in Lyon to exclude poloxamer 188. In Lyon, oil is an emulsion forming agent; oil is not a fluorocarbon. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the photosensitizer composition of the prior art where the broad teaching of poloxamer encompasses all poloxamers. One having ordinary skill in the art would have been motivated to prepare an emulsion composition comprising photosensitizing agents and poloxamer that may include or exclude poloxamer 188. In the absence of a showing of the criticality of including poloxamer 188, the claims in the application are not inventive over the prior art.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Stewart et al. (WO 98/34644, provided by applicants in Form PTO 1449) discloses a composition comprising a photosensitizing agent and one or more physiologically acceptable carriers (page 28, lines 21-28). The photosensitizing agent is administered alone or with water or other pharmaceutically acceptable excipients in a liquid, gel or gelatinous composition (page

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29, lines 7-24). The photosensitizing composition comprises a poloxamer surfactant block copolymer (page 31, lines 25-27). Stewart's photosensitizing agents are benzoporphyrin compounds selected from BPD-MA, BPD-MB, BPD-DA and BPD-DB (page 27, line 9 and claims 4 and 21). Stewart discloses a method of reducing or preventing the effects of inflammation that results from injury to tissues and the method comprises the steps of contacting the injured tissue with the photosensitizing composition and exposing the treated tissue to light of the appropriate energy to photodynamically treat the injured tissue (abstract, page 1, lines 5-15). Stewart further discloses that the photosensitizing agent may be combined with one or more immunosuppressive agents to enhance the anti-inflammatory effect of the photosensitizing agent (page 30, lines 10-13). The poloxamer block copolymer of Stewart encompasses all form the poloxamer. The emulsion-forming agent is a fluorocarbon.

11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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